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- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
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- ☐ Assignment Papers *(for an Application)*
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Remarks

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In The United States Patent Office

In re Application of Juan Luis HANCKE
et al., *Diterpenic Lambdanes...*

Art Unit 1625
Serial No. 10/516,500
Filed 3 February 2004

APPEAL BRIEF

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INTRODUCTION

This APPEAL BRIEF is submitted pursuant to the earlier-submitted renewed NOTICE OF APPEAL. The large-entity fee for filing an appeal brief has been filed previously. This APPEAL BRIEF is filed within two months of the earlier-submitted NOTICE OF APPEAL. No extension of time fee is therefore believed due.

This patent application has been granted Special status. Expedited resolution of this appeal is therefore respectfully requested.

Real Party In Interest

The real party in interest is HP Ingredients, Inc., a Florida corporation.

Related Appeals and Interferences

There are no related appeals nor interferences known to appellant, the appellant's legal representative, nor the assignee which may be related to, directly affect nor be directly affected by or have a bearing on the Board's decision in the immediate appeal.

Status of Claims

Claims 1 to 52 stand cancelled. Claims 53 to 73 are pending and stand finally rejected. Appellant appeals the rejection of all pending claims.

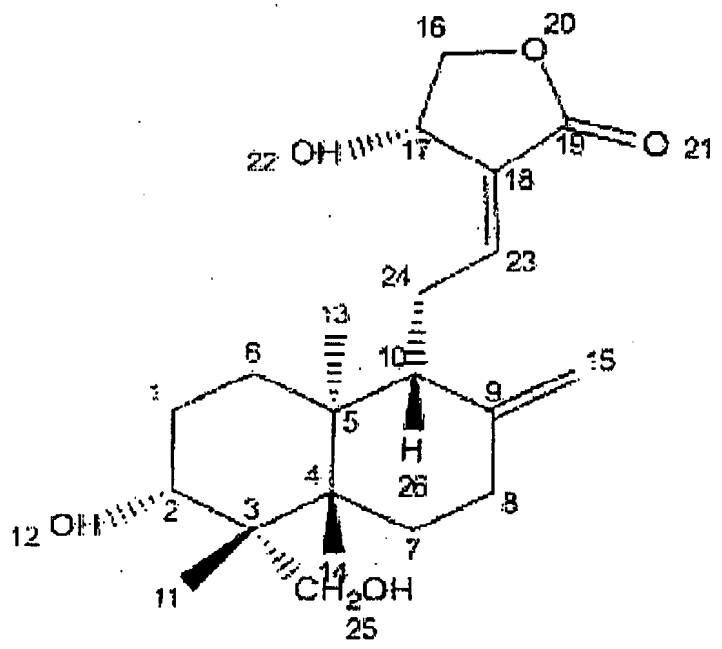
Status of Amendments

No amendment has been filed subsequent to the Final rejection.

Summary of Claimed Subject Matter

The invention relates to a compound chemically known as (3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone), and to the use of this compound to treat certain medical conditions.

The inventors believe that this compound is effective in modulating the activity of the human immune system, and will therefore be effective in treating conditions exhibiting an under-active or over-active immune response.



Three independent claims are pending. Independent claim 53 claims the use of 3-[2 [decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl] ethylidene]- dihydro-4-hydroxy-2(3h)-furanone to treat autoimmune disease, Acquired Immune Deficiency Syndrome or Alzheimer's Disease. *See e.g.*, SPECIFICATION at 13:1 *et seq.*; 2:23 *et seq.*; 6:9 *et seq.*[1]

Independent claim 66 claims the use of 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone to modulate a patient's immune system function (e.g., to activate peroxysome proliferator activated receptor gamma. *E.g., id.* at 6:9 *et seq.*

Independent claim 73 claims the use of 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone to treat "syndrome X," a condition which the inventors believe is caused by immune system dysfunction. *E.g., id.* at claim 73.

Grounds of Rejection to be Reviewed on Appeal

The sole grounds for rejection presented on appeal is as follows:

1) Whether the OFFICE ACTION states a *prima facie* case that any claim is anticipated under 35 U.S.C. Section 102(b)?

[1] To avoid confusion, all references to the Specification are to the clean (not the black lined) version of the SUBSTITUTE SPECIFICATION received by the Office on 02 December 2004.

Argument

Applicant respectfully believes the Examiner has failed to make of record evidence showing that any claim is anticipated; to the contrary, the Examiner fails to even allege a *prima facie* case.

The claims which are argued separately are placed under sub-headings including the relevant claim number.

The EXAMINER Fails To State A *Prima Facie* Case Of Anticipation

Claims 53 to 73 stand rejected as anticipated. In making her rejection, the Examiner relies on nine (9) references of record and two (2) alleged references which are not of record. Despite this plethora of evidence, however, the Examiner nonetheless fails to establish -nor even allege - a *prima facie* case of anticipation.

BABISH FAILS TO TEACH EVERY ELEMENT OF ANY PENDING CLAIM

The Examiner says that the claims are anticipated by (1) John G. BABISH *et al.*, U.S. Patent Publication No. 2002/0068098 (2002), *see* Office Action (19 January 2007) at 3, or (2) John G. BABISH *et al.*, U.S. Patent Publication No. 2002/0077350 (2002), *see id.* at 5, or (3) John G. BABISH *et al.*, WO96/17605 (1996), *see id.* at 6.

To anticipate, however, a single reference must teach each and every element of the claimed invention. *E.g., Moba, B.V. v. Diamond Automation, Inc.*,

325 F.3d 1306 (Fed. Cir., 2003). In the immediate case, the Examiner fails to allege that any of the references teaches every element of any claim.

BABISH fails to teach every element of claim 53

Independent claim 53 claims the use of 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone to treat Alzheimer's Disease, Acquired Immune Deficiency Syndrome or autoimmune disease:

> 53. A method comprising:
>
> i) diagnosing in a patient a disease selected from the group consisting of: Alzheimer's Disease; Acquired Immune Deficiency Syndrome; and autoimmune disease, and
>
> ii) administering to said patent 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone in an amount effective to combat said disease.

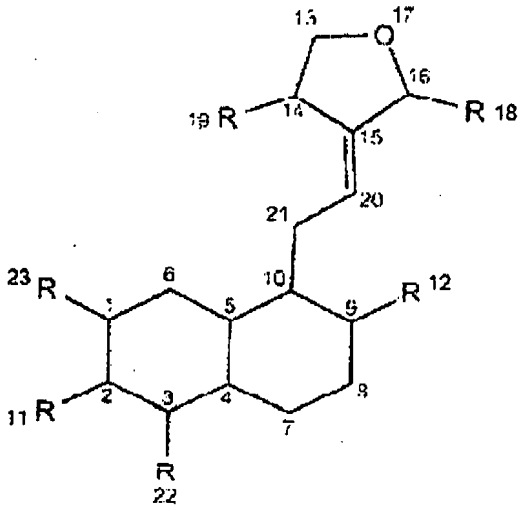
The Examiner alleges that BABISH (1996) at 16:25-26 teaches a compound "having activity as Alzheimer's, AID's." *See* Office Action (17 Jan. 2007) at 6. The Examiner is incorrect because BABISH (1996) at 16:25-26 fails to mention Alzheimer's, nor AIDS, nor indeed *any therapeutic action at all.*

Similarly, the Examiner alleges that BABISH (2002) at 5 teaches a compound "having the activity such as anti-inflammatory, Alzheimer's disease, antihyperlipidemia, antitumor, colon cancer." *See* Office Action (17 Jan. 2007) at 5.

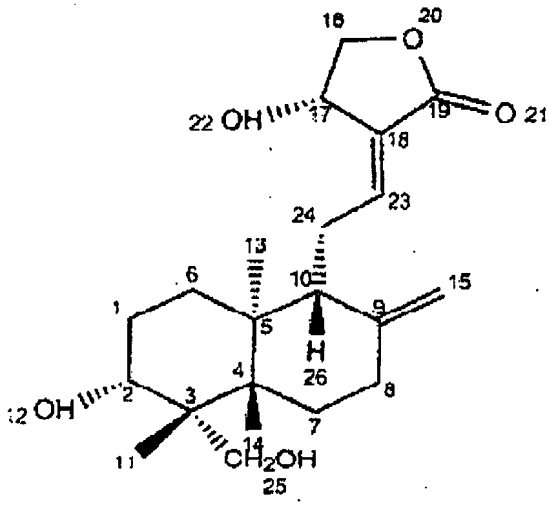
This is incorrect because BABISH (2002) at 5 fails to mention clinical use as an anti-inflammatory, or to treat Alzheimer's disease, or for anti-hyperlipidemia, or as an anti-tumor agent, or to treat colon cancer. Rather, BABISH (2002) at page 5 mentions one - and only one - potential clinical use for his compound: as an adjunct to improve the effectiveness of COX-2 enzyme inhibitors.

Similarly, BABISH teaches a broad variety of chemical compounds. These compounds, however, are ***different from*** the claimed compound. This is perhaps most easily shown by comparing the structure of the claimed compound to the structures for the various compounds taught by BABISH.

The claimed compound is 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone. In contrast, BABISH (1996) teaches compounds which differ in a number of aspects. *See e.g.*, BABISH (1996) at Fig. 6 (reproduced below). For example, the prior art compounds (unlike the claimed compound) have an R group at C1, the prior art compounds lack the CH3 and CH2OH groups at C3, and the prior art compounds lack the double bond at C9.



John G. BABISH *et al.*, WO '605



The claimed compound

Similarly, John G. BABISH *et al.*, U.S. Patent Publication No. 2002/0068098 (2002) and John G. BABISH *et al.*, U.S. Patent Publication No. 2002/0077350 (2002) each teach a compound which is different from the claimed compound.

The Examiner ***concedes*** that BABISH (2002) teaches a different structure. The Examiner ***concedes*** that the claimed structure "could not be found in" BABISH. *See e.g.*, Office Action (17 Jan 2007) at 6, *citing* BABISH (1996).

The Examiner, however, opines that BABISH teaches an incorrect structure, because BABISH includes a critical typographical error. *See e.g.*, Office Action (19 Jan 2007) at 3-4 ("the (=O) in the prior art structure on sheet 2, Fig. [B3]

is typo."). The Examiner thus opines that if BABISH had taught the structure correctly, without typographical error, then BABISH's structure "*should* be the same as" the claimed compound. In other words, the Examiner does not limit her inquiry to what the prior art actually taught, but what it should have taught.

The Examiner's argument, however well intended, fails as a matter of law because it is legally immaterial and because it is factually baseless.

The Examiner's allegation is immaterial because the typographical error alleged is not relevant to an anticipation inquiry. BABISH teaches what BABISH teaches. Assuming that BABISH inadvertently teaches an incorrect compound, no legal authority empowers the Examiner to modify that reference to make it teach what it ostensibly *should have* taught ten years ago. Assuming that BABISH inadvertently teaches the incorrect compound, his error fails to change a flawed reference into a valid one. (To the contrary, it indicates that BABISH fails to enable the claimed compound, and thus fails to anticipate).

The Examiner's allegation is factually baseless because she has produced no evidence that BABISH in fact intended to publish a different structure.

The Examiner attempts to prove the structure which BABISH ostensibly should have taught by relying on "the STN REGISTERY." *See* Office Action at 4. The Examiner's reliance is misplaced for two reasons.

First, the "STN REGISTERY" is not of record in this proceeding. Given the Examiner's difficulty in accurately summarizing the evidentiary substance of the references which ***are*** of record, the Applicant cannot blindly accept the Examiner's interpretation of a reference which is not of record.

Second, the Examiner fails to introduce any evidence showing that John G. Babish and his co-authors in fact intended their 2002 publications to teach a compound different from the one they expressly taught, whether that compound be culled from the "STN REGISTERY," from a third-party patent, or from any other source.

The Examiner also attempts to prove the structure which BABISH ostensibly should have taught by relying on a compound allegedly commercially available from "Aldrich Chemicals." *See* Office Action at 6. The Examiner's reliance is misplaced because no evidence of record shows what that on-sale compound actually was.

BABISH fails to teach every element of claim 66

Independent claim 66 is a treatment requiring "an amount effective to affect said patient's immune system function." The Examiner fails to allege where BABISH enables - nor even mentions - the claimed amount.

BABISH fails to teach every element of claim 73

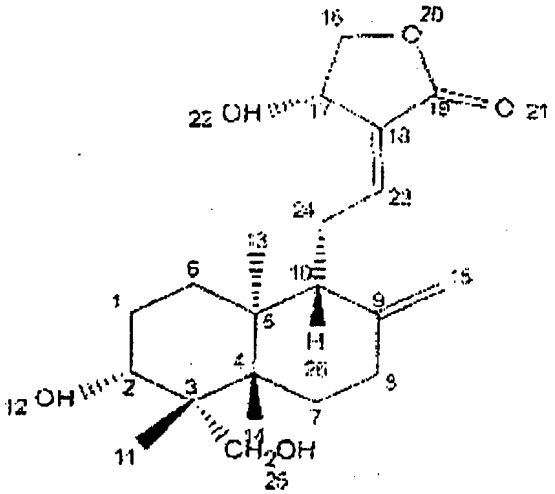
Independent claim 73 is a treatment for Syndrome X. The Examiner fails to allege where BABISH teaches - nor even mentions - Syndrome X.

WHEELOCK FAILS TO TEACH EVERY ELEMENT OF ANY PENDING CLAIM

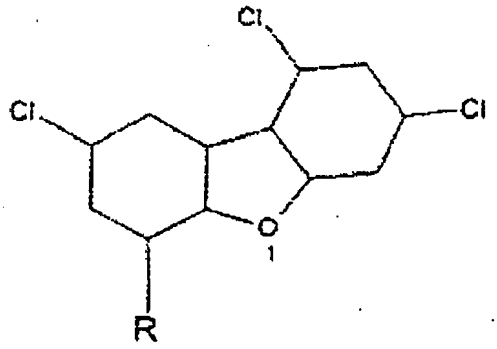
WHEELOCK fails to teach every element of claim 53

The Examiner says that the claims are anticipated by Geoffrey D. WHEELOCK *et al.*, U.S. Patent No. 5,833,994 (1998); or Geoffrey D. WHEELOCK *et al.*, WO 98/30213 (1998), or Geoffrey D. WHEELOCK *et al.*, U.S. Patent No. 6,140,063 (2000). Applicant respectfully disagrees because WHEELOCK fails to teach the claimed compound.

Independent claim 53 requires 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone. In contrast, WHEELOCK teaches dibenzofuran compounds with a substituted R moiety. *See e.g.*, WO '213 at page 17, US '994 at 11:40 to 12:55. These compounds are quite different, as shown in the Figure:



The Claimed Compound



Geoffrey D. WHEELOCK *et al.*

WHEELOCK fails to anticipate the claim because it fails to teach the claimed compound. The Examiner ***concedes*** that the claimed structure "could not be found in" WHEELOCK. *See e.g.*, Office Action (17 Jan 2007) at 4.

The Examiner, however, recognizes that WHEELOCK teaches that dibenzofuran compounds are useful as Ah-receptor antagonists. *See e.g.*, US '994 at 21:49-52. The Examiner correctly notes that WHEELOCK teaches testing dibenzofurans with a compound or class of compounds which WHEELOCK calls "andrographolide." *See id.* ("Anti-Cancer Effects of Andrographolide and its Synergistic Use with Ah Receptor Antagonists"). The Examiner then alleges that WHEELOCK's "andrographolide" is the claimed compound.

This allegation fails because it is factually baseless - to the contrary, it is ***contradicted*** by the only evidence of record. The evidence of record teaches that the compound(s) called "andrographolide" has (have) a chemical structure(s) which is (are) different from the claimed compound. *See e.g.*, BABISH (2002) at Figure 2[B2], Srinivas NANDURI *et al.*, U.S. Patent No. 6,410,590 (2002) at 2:26-42 and at 1:15-30. Further, the evidence of record corroborates the inventor's testimony that the term "andrographolide" is ill-defined and has different meanings in the art. *See* J.L. HANCKE, RULE 132 DECLARATION (9 September 2006) at ¶ 6

The Examiner counters that WHEELOCK uses the term "andrographolide" to denote a compound taught not by BABISH, nor the compounds taught by NANDURI, but the compound taught by "the STN REGISTERY." This argument fails for two reasons.

First, "the STN REGISTERY" is not of record in this proceeding.

Second, no evidence of record indicates that Geoffrey D. Wheelock and his co-inventors in fact intended the term "andrographolide" to mean the "STN REGISTERY" compound, rather than the compound taught by BABISH nor the compounds taught by NANDURI.

WHEELOCK fails to teach every element of claim 66

Independent claim 66 is a treatment requiring "an amount effective to affect said patient's immune system function." The Examiner fails to allege where WHEELOCK enables - nor even mentions - the claimed amount.

WHEELOCK fails to teach every element of claim 73

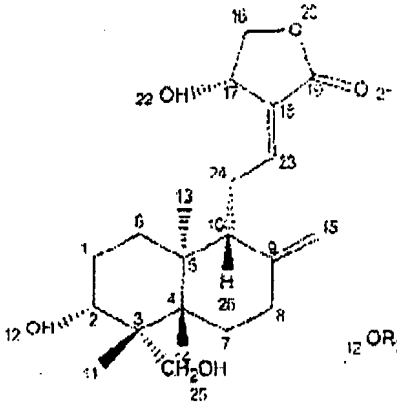
Independent claim 73 is a treatment for Syndrome X. The Examiner fails to allege where WHEELOCK teaches - nor even mentions - Syndrome X.

NANDURI FAILS TO TEACH EVERY ELEMENT OF ANY PENDING CLAIM

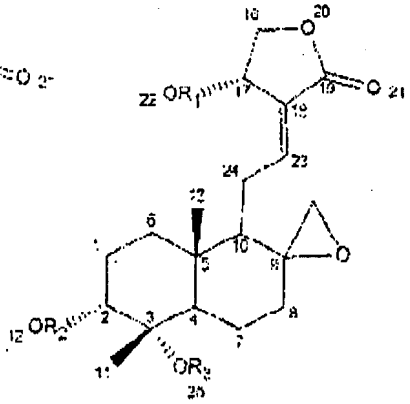
NANDURI fails to teach every element of claim 53

The Examiner says that the claims are anticipated by Srinivas NANDURI *et al.*, U.S. Patent No. 6,410,590 (2002); Srinivas NANDURI *et al.*, U.S. Patent No. 6,486,196 (2002); or Srinivas NANDURI *et al.*, U.S. Patent Publication No. 2002/0016324 (2002).

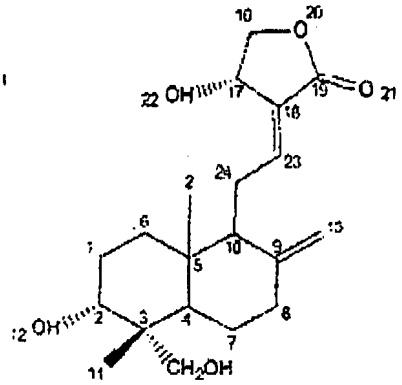
Applicant respectfully disagrees because NANDURI fails to teach the claimed compound. To the contrary, NANDURI teaches structurally different compounds. NANDURI teaches "Andrographolide having the formula (II)," *see e.g.*, U.S. '590 at 2:26-43, and "Andrographolide having the general formula (I)," *see id.* at 1:14-30. These compounds differ from the claimed compound. These differences may perhaps be seen most easily by comparing the respective chemical structures:



The Claimed Compound



Srinivas NANDURI *et al.*,
"Andrographolide having the general formula (I)"



Srinivas NANDURI *et al.*,
"Andrographolide having the formula II"

The Examiner argues that "the structure and the name is the same as the instant claims." *See* Office Action at 8. Applicant respectfully disagrees. The structures differ quite clearly, as shown in the above illustration. Similarly, the chemical names are different; pointedly, NANDURI fails to even ***mention*** 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone, much less equate that compound to "andrographolide having the general formula (I)" nor "andrographolide having the formula (II)."

NANDURI fails to teach every element of claim 66

Independent claim 66 is a treatment requiring "an amount effective to affect said patient's immune system function." The Examiner fails to allege where NANDURI enables - nor even mentions - the claimed amount.

NANDURI fails to teach every element of claim 73

Independent claim 73 is a treatment for Syndrome X. The Examiner fails to allege where NANDURI teaches - nor even mentions - Syndrome X.

NO PENDING REJECTION IS SUSTAINABLE

No art of record teaches the claimed compound. *See* J.L. HANCKE, RULE 132 DECLARATION (9 September 2006) at ¶¶ 7-9; J.L. HANCKE, SUPPLEMENTAL RULE 132 DECLARATION (20 September 2006) at ¶¶ 1-4.

Further, the Examiner concedes that the predictability in the pharmaceutical art is low, because minor structural differences can precipitate major changes in toxicology or clinical efficacy. This shows that it would not have been obvious to modify any of the prior art cmpounds to *make* the claimed compound, and that it would not have been obvious to *use* such a modified compound for the claimed uses.

Similarly, the claims are drawn to methods to treat AIDS, Syndrome X, non-autoimmune Alzheimer's Disease, and autoimmune disease. In contrast, the art of record fails to teach these therapeutic uses. *See* J.L. HANCKE, RULE 132 DECLARATION (9 September 2006) at ¶¶ 7-9.

Applicant respectfully requests the Board reverse all pending rejections and order the Examiner to issue a NOTICE OF ALLOWANCE.

Respectfully submitted on behalf of the Applicant by its attorneys,
PHARMACEUTICAL PATENT ATTORNEYS, LLC

/s/
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10 April 2007

SD:/HP Ingredients/1-.516,500 Appeal Brief (April 2007)

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CLAIMS APPENDIX

53. A method comprising:

i) diagnosing in a patient a disease selected from the group consisting of: Alzheimer's Disease; Acquired Immune Deficiency Syndrome; and autoimmune disease, and

ii) administering to said patent 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone in an amount effective to combat said disease.

54. The method of claim 53, wherein said disease comprises autoimmune disease.

55. The method of claim 54, wherein said autoimmune disease comprises rheumatoid arthritis.

56. The method of claim 54, wherein said autoimmune disease comprises lupus exanthematous.

57. The method of claim 54, wherein said autoimmune disease comprises multiple sclerosis.

58. The method of claim 54, wherein said autoimmune disease comprises asthma.

59. The method of claim 54, wherein said autoimmune disease comprises allergic reaction.

60. The method of claim 54, wherein said autoimmune disease comprises a condition selected from: systemic dermatomyocytis; and psoriasis.

61. The method of claim 54, wherein said autoimmune disease comprises osteoarthritis.

62. The method of claim 54, wherein said autoimmune disease comprises diabetes mellitus.

63. The method of claim 54, wherein said an amount effective to combat said disease comprises from about 1 mg to about 5 mg of 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone per day, per kilogram of patient body weight.

64. The method of claim 53, wherein said disease comprises Alzheimer's Disease.

65. The method of claim 53, wherein said disease comprises Acquired Immune Deficiency Syndrome.

66. A method comprising:

i) diagnosing in a patient a disease, and

ii) administering to said patent 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone in an amount effective to affect said patient's immune system function.

67. The method of claim 66, wherein said amount effective comprises an amount effective to activate peroxysome proliferator activated receptor γ.

68. The method of claim 66, wherein said amount effective comprises an amount effective to reduce the activity of an inflammatory cytokine.

69. The method of claim 68, said inflammatory cytokine comprising interleukin-2.

70. The method of claim 68, said inflammatory cytokine comprising interferon γ.

71. The method of claim 66, wherein said amount effective comprises an amount effective to inhibit NFκB.

72. The method of claim 66, wherein said amount effective comprises an amount effective to inhibit T-cell proliferation.

73. A method comprising:

i) identifying in a person the possible presence of Syndrome X, and

ii) administering to said person a substance selected from the group consisting of: *Andrographis paniculata*; and an *Andrographis paniculata* extract containing 3-[2-[decahydro-6-hydroxy-5-(hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]ethylidene]-dihydro-4-hydroxy-2(3h)-furanone; said substance administered in an amount effective to combat Syndrome X.

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EVIDENCE APPENDIX

The two Rule 132 Declarations previously submitted in this case, and all other evidence relied on, has been submitted before filing of the NOTICE OF APPEAL. Physical copies of this evidence is not included here because the Board has access to this evidence via the PAIR system.

RELATED APPEALS APPENDIX

None.